



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/580,650

05/25/2006

Svend Erik Borgesen

BORGESEN5A

5770

1444 7590 01/09/2009
BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

01/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,650	Applicant(s) BORGESEN, SVEND ERIK	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,20,24,26-38,48 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,20,24,26-38,48 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 5, 24, 26-31, 37, 38, 48, and 60 rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,283,934 to Borgesen in view of WO 95/19796 to Valentini.

In the specification and figures, Borgesen discloses the method and apparatus substantially as claimed by applicant.

With regard to claims 1 and 37, Borgesen discloses the apparatus substantially as claimed by applicant. In particular, Borgesen discloses a system for shunting excess cerebrospinal fluid from a brain ventricle to a patient's sinus system, particularly, the saggital sinus (see column 1, lines 10-17, column 2, lines 58-65). The shunt system comprises:

a. a shunt body 12 allowing fluid communication between a ventricle 14 and saggital sinus 15, wherein the shunt body comprises or flow restricting component 3 capable of maintaining a constant resistance to fluid flow (see FIGS 6, 8, column 4, lines 20-23, column 6, column 7, line 65 to column 8, line 25),

- b. brain ventricle catheter 13 capable of being connected to the shunt body and draining CSF from the ventricle to the shunt body (see at least FIG 8)
- c. a sinus catheter (seen generally at reference numeral 7 in FIG 2, unlabeled in FIG 8) connected to the shunt body (see FIG 8), wherein the sinus catheter is capable of draining to the sinus system the fluids from the ventricle, and passed through the flow restrictor.

The apparatus, including shunt body, ventricular, and sinus catheter, are disclosed as being made of a biocompatible material (see, generally, column 6).

Borgesen fails to disclose that the surface of the shunt is coated with a plurality of charged species. However, Valentini discloses a biocompatible implant that is coated with an electrically charged material in order to enhance blood compatibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a known material such as the electrically charged material as disclosed by Valentini to the shunt apparatus disclosed by Borgesen in order to improve blood compatibility, as taught by Valentini.

With regard to claims 2, 5, 24, Borgesen discloses that the flow restricting structure and the tubes provide a resistance to flow of about 8 to 12 mm Hg/mL/min, which includes values just less than 8 (see column 6, lines 42-45). It is the position of the Examiner that the flow restricting component is *capable* of providing the flow resistance claimed by applicant.

With regard to claim 26, Borgesen discloses that the flow restricting passage comprises a tubular structure (see column 6, line 42).

With regard to claims 27-30, Borgesen discloses that the internal radius of the flow-restricting passage may be 0.15mm and the length 22.1mm (which may be divided into two parts), which is within the range claimed by applicant (see column 6, lines 42-50).

With regard to claim 31, Borgesen discloses that the apparatus may comprise a check valve 8 (see column 8, line 18).

With regard to claim 38, Borgesen discloses that the shunt body comprises a body and antechamber 2 made of the claimed materials (see column 6, lines 27-42). The apparatus comprises a tapering tip 7, 7' to which a catheter can be secured, wherein the antechamber 2 is connected to the tubular flow restricting element 3 so that the chamber forms an inlet to the restricting component, wherein the check valve (represented as ball 4) is arranged between the antechamber and the flow restricting element, wherein the apparatus comprises the drain and catheters claimed by applicant (see FIGS 6-8 and accompanying text).

With regard to claim 48, Borgesen discloses a method for implanting the claimed shunt wherein the shunt is placed subcutaneously on the top of the calvarium, inserting the catheters, connecting the catheters, and allowing fluidic communication between the catheters (see column 6, lines 12-23, column 8, line 59 to column 10 line 5).

With regard to claim 60, Borgesen further discloses the steps of inserting the ventricular catheter into the patient, inserting the sinus catheter into the patient, connecting the catheters to the shunt body, and removing toxic substances, such as excess CSF, from the ventricle to the sinus (see column 8, lines 27-47).

2. In addition to the rejection presented above, claims 1, 2, 5, 10, 20, 24, 26-48, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0045847 to Borgesen in view of WO 95/19796 to Valentini.

With regard to claims 1 and 37, Borgesen discloses a system for shunting excess cerebrospinal fluid from a brain ventricle to a patient's sinus system, which may comprise the transverse sinus (see paragraphs 0002, 0003, 0058). The shunt system comprises:

- a. a shunt body 10 allowing fluid communication between a ventricle 21 and ventricular sinus, wherein the shunt body comprises a flow restricting component 16 capable of maintaining a constant resistance to flow (see FIG 8, paragraph 0052),
- b. brain ventricle catheter 15 capable of being connected to the shunt body and draining CSF from the ventricle to the shunt body (see at least paragraph 0053)
- c. a sinus catheter 18 (see at least paragraph 0055) connected to the shunt body, wherein the sinus catheter is capable of draining to the sinus system the fluids from the ventricle, and passed through the flow restrictor.

The apparatus, including shunt body, ventricular, and sinus catheter, are disclosed as being made of a biocompatible material (see, generally, paragraph 0052).

Borgesen fails to disclose that the surface of the shunt is coated with a plurality of charged species. However, Valentini discloses a biocompatible implant that is coated

Art Unit: 3761

with an electrically charged material in order to enhance blood compatibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a known material such as the electrically charged material as disclosed by Valentini to the shunt apparatus disclosed by Borgesen in order to improve blood compatibility, as taught by Valentini.

With regard to claims 2, 5, 20, and 24, Borgesen discloses that the flow restricting structure and the tubes provide a resistance to flow of less than 8 mm Hg/mL/min, preferably 4-6 mm Hg/mL/min (see paragraph 0031).

With regard to claim 26, Borgesen discloses that the flow restricting passage comprises a tubular structure (see paragraph 0026).

With regard to claims 27-30, Borgesen discloses that the internal radius of the flow-restricting passage may be less than 0.20mm and the length 22.1mm (which may be divided into two parts), which is within the range claimed by applicant (see paragraphs 0033, 0035, 0036).

With regard to claims 31-36, Borgesen discloses that the apparatus may comprise a mitral silicone check valve wherein the check valve provides no fluid resistance to the CSF, rendering fluid flow resistance independent of the check valve with the check valve operating independently of the fluid pressure threshold (see paragraph 0040).

With regard to claim 38, Borgesen discloses that the shunt body comprises a body and antechamber 11 with opposite flat walls 12 made of the claimed materials (see paragraph 0052). The top walls of the chamber end in tip 14, to which a ventricular

catheter 15 may be attached. The distal end of chamber 11 has an inlet to tubular flow restriction 16 with a check valve 17 placed therebetween. Fluidic connection to the sinus system is provided by drain 18 and fluidic connection to the brain ventricle is provided by ventricle catheter 15 (see paragraph 0052).

With regard to claim 48, Borgesen discloses a method for implanting the claimed shunt wherein the shunt is placed subcutaneously on the top of the calvarium, inserting the catheters, connecting the catheters, and allowing fluidic communication between the catheters (see paragraph 0031).

With regard to claim 60, Borgesen further discloses the steps of inserting the ventricular catheter into the patient, inserting the sinus catheter into the patient, connecting the catheters to the shunt body, and removing toxic substances, such as excess CSF, from the ventricle to the sinus (see paragraph 0032).

Response to Arguments

3. Applicant's arguments, filed 5 November 2008, with respect to the rejection(s) of the amended claim(s) under Borgesen have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Borgesen and Valentini, as presented above.

4. Applicant argues that the materials disclosed by Borgesen do not necessarily and inherently demonstrate the properties of the instantly claimed material. The Examiner agrees that the addition of the charged species limitation to the claims

narrows the scope of Applicant's claim, and has relied on a secondary reference to teach the use of such a material.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
7 January 2009